November 17, 2004

Office of Special Nutritionals (HFS-450) Center for Food Safety and Applied Nutrition Food and Drug Administration 200 C St. SW., Washington, D.C. 20204

DFC 0 2 2004

RE: Notification of Nutritional Support Statements

To whom it may concern:

I hereby notify the Food and Drug Administration (FDA) of the use of statements of nutritional support in the labeling of Guggulsterones, a dietary supplement. Source Naturals[®] is the manufacturer of Guggulsterones.

Statements being made in the labeling of Guggulsterones

- 1) Guggulsterones help maintain cholesterol levels already in the normal range, by acting at the farnesoid X receptor (FXR) to promote the conversion of cholesterol into bile.
- 2) They also boost thyroid activity, which supports cholesterol regulation by the liver.

To the best of my knowledge and belief, and based upon information available at the time of the execution of this notice, I certify that the above information is accurate and complete. Source Naturals[®] possesses substantiation that the statements are truthful and not misleading.

Ira L. Goldberg

President, Source Naturals®

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QUOY